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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,993	04/06/2006	E. Premkumar Reddy	35926032901US	2185

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EXAMINER	
NWAONICHA, CHUKWUMA O	
ART UNIT	PAPER NUMBER
1621	
MAIL DATE	DELIVERY MODE
05/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,993	REDDY ET AL.	
	Examiner	Art Unit	
	Chukwuma O. Nwaonicha	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,32-38,69 and 77* is/are pending in the application.

4a) Of the above claim(s) *28-31,39-68 and 70-76* is/are withdrawn from consideration.

5)☒ Claim(s) *1-6,8-13,15,16,18,19,32-38 and 77* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☒ Claim(s) *7,14,17,20-27 and 69* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-77 are pending in the application.

The Election/Restrictions of 1/31/07 has been vacated in favor of a new restriction.

Lack of Unity

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1. Claims 1-27, 32-38, 69 and 77, drawn to compounds, wherein n is 1, their composition, process for making the compounds and method of using the compounds, classified in class 514, subclass 355+.

Group 2. Claims 1-27, 32-38, 69 and 77, drawn to compounds, wherein n is 0, their composition, process for making the compounds and method of using the compounds, classified in class 514, subclass 355+.

Group 3. Claims 27-31 and 39 drawn to a conjugate, its composition and method of treatment, classified in class 514, subclass 355+.

Group 4. Claims 40-54 drawn to a method of reducing or eliminating the effects of ionizing radiation, classified in class 514, subclass 355+.

Group 5. Claims 55-68 drawn to a method of protecting an individual from cytotoxic side effects, classified in class 514, subclass 339+.

Group 6. Claims 70 and 75 drawn to a compound of formula II and a process of making the same, classified in class 564, subclass 355+.

Group 7. Claim 71 drawn to a compound of formula II and a process of making the same, classified in class 546, subclass 315+.

Group 8. Claim 72 drawn to a process of making the compound of formula Iz, classified in class 568, subclass 63+.

Group 9. Claim 73 drawn to a process of making the compound of formula IV and a process of making the same, classified in class 546, subclass 315+.

Group 10. Claim 74 drawn to a process of making the compound of formula V and a process of making the same, classified in class 546, subclass 315+.

Group 11. Claim 76 drawn to compound of formula IV, classified in class 546, subclass 315+.

The inventions listed as Group 1 - Group 11 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group 1 and 2 are drawn to different compounds, their composition, process for making the compounds and method of using the compounds, Group 3 is drawn to a conjugate, its composition and method of treatment while Groups 4 and 5 are drawn to different methods of treating diseases. Group 6 is drawn to a compound of formula II and a process of making the same while Groups 7-10 are drawn to different methods for making different compounds, and Group 11 is drawn to a compound that is different from the compounds of Group 1 and 2. These eleven groups of invention are different

from each other. Therefore, there is no special technical feature for the compounds, the processes of making these compounds or the different fields of application of the compounds. Also there is no unity of invention.

There is no special technical feature, which unites the groups. But even if there were a special technical feature there must be unity of invention also. Under 37 CFR 1.475

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and a process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

The above groups 1-11 together do not meet the requirement of unity of invention as given above in (1) -(5).

During a telephone conversation with Daniel Monaco on 4/12/07, a provisional election was made with traverse to prosecute the invention of Group 1. Affirmation of this election must be made by applicant in replying to this Office Action. Groups 2-11 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Applicants are reminded of their right to file divisional applications to the non-elected claims.

Priority

Applicants' claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 34, 35, 37 and 38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation, does not reasonably provide enablement for "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive

myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis". Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not, because treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis;

ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" with the claimed compounds is speculative.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" with the claimed compounds.

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claims 33, 34, 35, 37 and 38** are *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (***In re* Wands**, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** As indicated above, the invention is drawn to treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation, and treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis". Specifically treating the above diseases with the claimed compound.

(2) **Breadth of the Claims.** The claims are extremely broad. In particular, **claims 33, 34, 35, 37 and 38** that read on specifically treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation, and treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis". Applicants have failed to exactly show how to treat "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis".

(3) State of the Prior Art. There is no known treatment with the claimed compound. The prior arts teach Certain alpha,beta-unsaturated sulfones, particularly styrylbenzyl sulfones have been shown to posses antiproliferative, radioprotective and chemoprotective activity as disclosed in U.S. Pat. Nos. 6,599,932, 6,576,675, 6,548,553, 6,541,475, 6,486,210, 6,414,034, 6,359,013, 6,201,154, 6,656,973 and 6,762,207.

(4) **Unpredictability of the Art.** The instant case is drawn to treating breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation, and treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis". "Treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" with compounds of present invention is speculative. Applicants' claim to treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular

restenosis" in with the claimed compounds is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. In re Fisher, 166 U.S.P.Q. 18.

(5) **Amount of Guidance Provided.** Applicants have provided no guidance for using the claimed method to treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis". However, when considering that the claims read on the treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis", it becomes critical to know how long does one administers the said compound to treat the diseases. This is critical to the practice of the invention and therefore should adequately be disclosed.

(6) **Presence or Absence of Working Examples.** There are no examples of treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" disclosed. Applicants only disclose few

examples showing the treatment of breast tumor, prostate tumor, lung tumor, colorectal tumor and therapeutic ionizing radiation with the claimed compounds.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. This is a new field with no known success for the treatment of "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" with the claimed compounds.

(8) **Amount of Experimentation Necessary.** A great deal of experimentation is required. In lieu of the fact that no animal models exist which can reasonably suggest successful treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" with the claim compounds, it will be necessary for an ordinary skilled artisan to have clinical data in order to practice the claimed invention.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for treating "proliferative disorder, cancer, hemangiomatosis in newborn; secondary progressive multiple sclerosis; chronic progressive

myelodegenerative disease; neurofibromatosis; ganglioneuromatosis; keloid formation; Paget's Disease of the bone; fibrocystic disease, sarcoidosis; Peronies and Duputren's fibrosis, cirrhosis, atherosclerosis and vascular restenosis" with the claimed compounds.

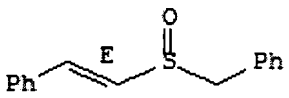
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

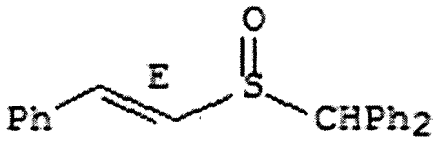
Claims 1 and 3 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhong, et al., {Simple and stereoselective synthetic route to (E)-1-alkenyl sulfoxides via terminal alkynes, Journal of Chemical Research, Synopses (2000), (12), 588-589}.

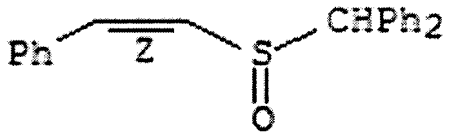
Zhong et al. disclose applicant's claimed compound as shown below. Also, see the compound in the abstract.

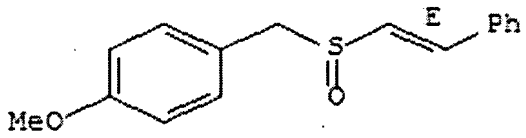


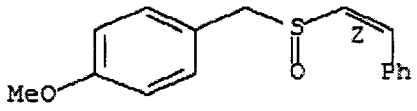
Claims 1-6, 8-13, 15, 16, 18, 19 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwan et al., {1-Alkenesulfinyl Chlorides: Synthesis, Characterization, and Some Substitution Reactions, Journal of Organic Chemistry (1998), 63(22), 7825-7832}.

Schwan et al. disclose applicant's claimed compounds as shown below. Also, see the compound in the abstract.



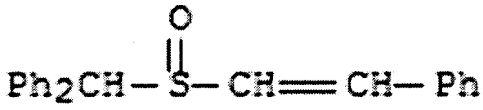


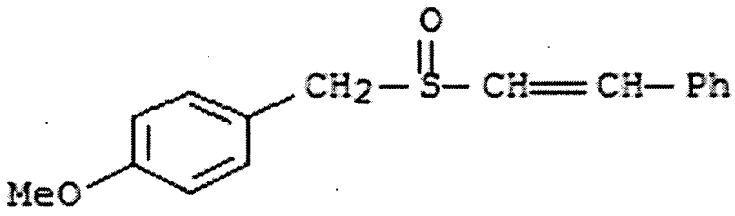




Claims 1, 4, 5, 6, 8-11, 15, 18 and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwan et al., {Oxidative fragmentations of selected 1-alkenyl sulfoxides. Chemical and spectroscopic evidence for 1-alkenesulfinyl chlorides, Tetrahedron Letters (1996), 37(14), 2345-8}.

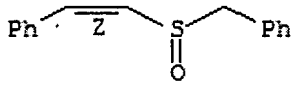
Schwan et al. disclose applicant's claimed compound as shown below. Also, see the compound in the abstract.





Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al., {Intermolecular transfer of the 2,4,6-trinitrophenyl group bound to amino radicals, Nippon Kagaku Zasshi (1962), (83), 895-901}.

Tanaka et al. disclose applicant's claimed compound as shown below. Also, see the compound in the abstract.



Allowable Subject Matter

Claims 7, 14, 17, 20-27 and 69 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chukwuma O. Nwaonicha, Ph.D.
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